## *Remarks*

### 1. Status of the Claims

Reconsideration of this Application is respectfully requested. Upon entry of the foregoing amendment, claims 28-39, 41, 43-47, and 55 are pending in the application, with claims 28 and 38 being the independent claims. Claims 28-37 were previously withdrawn in view of the Examiner's restriction requirement dated August 19, 2011. Claims 40, 42, and 48-54 are sought to be canceled without prejudice to or disclaimer of the subject matter therein. Claims 38, 39, 43, and 45 are sought to be amended. Support for the amendments to the claims can be found throughout the specification as filed, *e.g.*, at page 12, line 15 to page 13, line 28; and original claim 5. New claim 55 is sought to be added. Support for the new claim can be found in the specification as filed, *e.g.*, at page 14, line 30 to page 15, line 4. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### 2. Summary of the Office Action

In the Office Action the Examiner has raised one objection to the title of the invention and three rejections to the claims. Applicants respectfully offer the following remarks concerning the objection and rejections.

**3. Objection to the Title of the Invention**

At page 3 of the Office Action, the Examiner objected to the title of the invention as allegedly not being descriptive. Applicants have amended the title herein to "Alkaline phosphatase for treating an inflammatory disease of the gastro-intestinal tract." Applicants respectfully request that the objection to the title be reconsidered and withdrawn.

**4. Rejection Under 35 U.S.C. § 102(b)**

At page 2 of the Office Action, the Examiner has rejected claims 38-54 under 35 U.S.C. §102(b), as allegedly being anticipated by Poelstra, U.S. Pat. No. 6,290,952 ("Poelstra"). In particular, the Examiner asserts that Poelstra teaches pharmaceutical compositions with alkaline phosphatase activity used in a method where the composition is administered to treat pathology mediated by endotoxin. The Examiner alleges that all of the features of the claims are taught by Poelstra for the same function as claimed. Applicants respectfully disagree.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 361 (Fed. Cir. 1987)). There must be no difference between the claimed invention and the referenced disclosures, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic v. Milgraum*, 52 U.S.P.Q. 2d 1303 (Fed. Cir. 1999). In other words, "a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art. *Schering Corporation*

*v. Geneva Pharmaceuticals, Inc. and Novartis Corporation et al.*, 68 U.S.P.Q. 2d 1760 (Fed. Cir. 2003).

Solely to advance prosecution and without acquiescence to the Examiner's rejection, claim 38 has been amended to recite "...when the AP is delivered to the mucosa of the gastro-intestinal tract." Support for the amendment can be found, *e.g.*, in the specification as filed, *e.g.*, at page 12, line 15 to page 13, line 28; and original claim 5. Claims 39, 41, 43-47, and 55 depend directly or indirectly from claim 38 and therefore incorporate all of the limitations of claim 38. Furthermore, claims 40, 42, and 48-54 have been canceled, and therefore the rejection is moot with regard to these claims.

Poelstra does not teach all of the limitations of the claimed invention. In particular, Poelstra does not expressly or inherently teach or describe a method of administering AP at the mucosal layer of the gastro-intestinal (GI) tract in order to prevent or reduce LPS toxicity at the mucosal surface of the GI tract.

Poelstra discloses the dephosphorylation of endotoxin under physiological pH levels by AP both *in vitro* and *in vivo* as a natural response. However, the currently claimed invention is aimed at providing methods for administering AP for the detoxification of LPS at the mucosal layer of the GI tract, thereby detoxifying LPS before it can pass through the mucosal layer and enter the circulation where it would elicit toxic effects and/or an inflammatory response (*see* specification as filed, *e.g.*, at page 6, line 31 to page 7, line 2; and page 9, lines 20-28). Furthermore, due to the high

acid content in the gut, a person of ordinary skill in the art would not have predicted that AP administration at the mucosa of the GI tract would maintain its detoxifying activity.

In view of the above, it is respectfully submitted that Poelstra does not teach or describe each and every element of claims 38, 39, 41, 43-47, and 55 either expressly or inherently. Therefore, the claims are not anticipated by Poelstra, and Applicants respectfully request that the rejection of claims 38, 39, 41, 43-47, and 55 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

**5. Rejection Under 35 U.S.C. § 112**

Claims 38-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner asserts that the claims contain subject matter which was allegedly not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Office Action at pages 2-3. Furthermore, the Examiner alleges that the claims are directed to preventing and treating a plethora of disorders and that the study does not extend to treating (or preventing) the disorders claimed by administering AP to any mucosal surface of any body cavity to treat such disorders as all LPS toxicity which reads on meningitis to septicemia. Office Action at page 3. Applicants respectfully disagree.

Applicants disagree that claim 38 is "directed to preventing and treating a plethora of disorders." Claim 38 is directed to preventing or reducing LPS toxicity at the mucosal surface of a mammalian body cavity in a subject, comprising administering to the subject in need thereof a composition comprising a source of alkaline phosphatase (AP) that is suitable for preventing or reducing lipopolysaccharide (LPS)-induced

toxicity at a mucosal surface when the AP is delivered to the mucosa of the gastro-intestinal tract. As currently claimed, treatment or prevention of any disease or disorder is not part of the claim elements. As disclosed in the specification at page 10, lines 20-23, "the beneficial effects of AP administration...according to the current invention will generate a general health promoting effect regardless of the medical condition of the subject treated." Accordingly, whether or not the specification enables preventing or treating a plethora of disorders is not relevant to the current claim scope. The specification does enable preventing or reducing LPS toxicity at the mucosal surface of a mammalian body cavity in a subject according to the claimed method (*see*, *e.g.*, page 7, line 29 to page 8, line 18; page 8, line 27 to page 9, line 9; page 10, lines 20-23; page 12, line 15 to page 13, line 28; and page 26, lines 8-18). Thus, the claimed method is enabled.

Furthermore, solely to advance prosecution and without acquiescence to the Examiner's rejection, claims 39 and 43 have been amended to specify that the methods are directed to "...wherein the subject suffers from..." As amended, claims 39 and 43 as well as the claims that depend therefrom, do not require prevention or treatment of the claimed diseases or conditions. These claims, which depend directly or indirectly from claim 38, are directed to preventing or reducing LPS toxicity at the mucosal surface of a mammalian body cavity in a subject, and in certain embodiments, the subject can suffer from a claimed disease or condition, but as currently claimed, such disease or condition need not be treated or prevented. Furthermore, claims 40, 42, and 48-54 have been canceled, and therefore the rejection is moot with regard to these claims.

In view of the above, it is respectfully submitted that claims 38, 39, 41, 43-47, and 55 are enabled. Applicants respectfully request that the alleged lack of enablement rejection of claims 38, 39, 41, 43-47, and 55 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

**6. Rejection Under 35 U.S.C. § 112**

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter of which the applicant regards as the invention. In particular, the Examiner asserts that in claim 39, "the prevention or reduction" lacks definite antecedent basis and is inconsistent with claim 38 from which it depends.

As discussed above, solely to advance prosecution and without acquiescence to the Examiner's rejection, claim 39 has been amended to specify that the methods of claims 39 are directed to "...wherein the subject suffers from...." As amended, claim 39 has proper antecedent basis and is consistent with claim 38 from which it depends.

Accordingly, it is respectfully submitted that claim 39 as amended is not indefinite. Applicants respectfully request that the rejection of claim 39 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

***Conclusion***

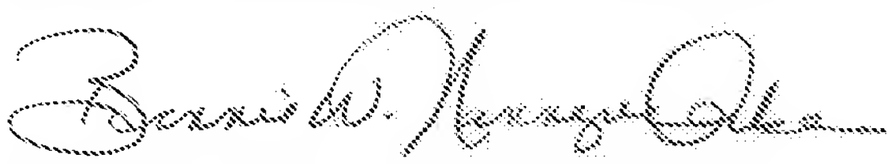
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the

outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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